UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,241	12/21/2001	L. Kathryn Durham	PC11028AGPR	6632

7590 03/25/2003

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,241	DURHAM ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 34-37, drawn to a method for determining whether a subject has a modified susceptibility to cardiovascular disease, classified in class 435, subclass 6.

II. Claims 6, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least 11 nucleotides of SEQ ID NO: 6 and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

III. Claims 6, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least 11 nucleotides of SEQ ID NO: 6 and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

IV. Claims 6, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least 11 nucleotides of SEQ ID NO: 8 and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

V. Claims 6, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least 11 nucleotides of SEQ ID NO: 10 and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

VI. Claims 6, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least 11 nucleotides of SEQ ID NO: 12 and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

VII. Claims 6, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least 11 nucleotides of SEQ ID NO: 14 and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

VIII. Claims 7, 8, 9, 10, 11, 12, 13, 14, 15 drawn to an isolated nucleic acid comprising at least one GAAA repeat and kits comprising said nucleic acid, classified in class 536, subclass 24.1.

IX. Claims 16-30, drawn to methods of treating patients, classified in class 514, subclass 44, for example.

X. Claims 31-37, drawn to methods of detecting cardiovascular disease via an activity assay, classified in class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I is related to inventions II-VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention II-VIII can be used in a variety of other methods, such as amplification methods, the expression of polypeptides, to drive promotion of a heterologous protein (invention VIII), and nucleic acid purification methods.

3. Inventions I and IX and inventions I and X and inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are drawn to

methodologies that have separate goals and/or separate outcomes and/or utilize separate method steps and/or separate reagents.

4. Inventions II -VIII are each drawn to distinct products. These inventions each comprise nucleic acids for the specific detection of polymorphisms in the CETP gene. Each separate invention is drawn to a nucleic acid that has a separate structure encoding distinct portions and variations of the gene.

5. Inventions II-VIII are unrelated to inventions IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are unrelated because the methods of invention IX and X do not recite or require the products of inventions II-VIII.

Further Restriction Requirement

Group I, IX and X include method steps that requires the detection or presence of "at least one" of six different recited polymorphisms. Groups II-VIII contain kits that contain reagents for the detection of "at least one" of six different polymorphisms. Thus, the claims read on a multitude of groupings of polymorphisms, each of which is separate and distinct one from another because they contain nucleic acid sequences that are structurally separate from one another. The search and examination of all possible groups would pose an enormous burden on the examiner and on the PTO search resources. In accordance with MPEP 803.04, applicant is required to select one combination of polymorphisms selected from those listed in the claims for examination with whichever group is elected. If applicant elects one of groups II-VIII, the

individual elected nucleic acid will be examined as well as the single combination elected by applicant for examination.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-X require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

March 22, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600